

Remarks

In the Advisory Action mailed August 20, 2009, the Examiner indicates that the rejection of claim 57 under 35 U.S.C. §103 based on Majeti in view of Stanley et al. has been withdrawn; and the Examiner further indicates that claim 57 is "objected to". Accordingly, claim 57 has been rewritten in independent form, incorporating the limitations of claim 10 from which claim 57 depended. Amended claim 57 is thus considered to be allowable on the record.

In response to the continuation of item 11 on the Continuation Sheet attached to the Advisory Action, Applicants again note that, when solubilizing drugs by micelle formation as taught by Story et al., excess amounts of surfactants are required in order to allow micelle formation to occur. The skilled person would have been led away from incorporating high proportions of surfactants (more than 10-fold excess) into the compositions described by Majeti (transdermal patch, buccal patch, bioadhesive film, mucoadhesive film) since high amounts of surfactants would be expected to reduce the mechanical strength of the films. Also, surfactants often exert plasticizing effects in polymer-based compositions (e.g. the film compositions described by Majeti). Therefore, the skilled person would not have considered the possibility of adding micelle-forming concentrations of surfactants into a polymeric film composition as this would be expected to destroy or deteriorate the mechanical properties of the film.

That is, Story et al. essentially require the surfactants to be added in amounts sufficiently high to promote micelle formation. Generally, excess amounts of surfactants have to be added to ensure that micelle formation will occur (see drug/surfactant ratios indicated, for instance, in Examples 1, 12, 24, 28, 36, 45, 52, 59, 95 and 104 of Story et al.). As discussed above, incorporating such high concentrations of surfactants would be expected to be incompatible with the presently claimed film compositions (whereas Story et al. are concerned with different types of administration forms, such as capsules and solutions).

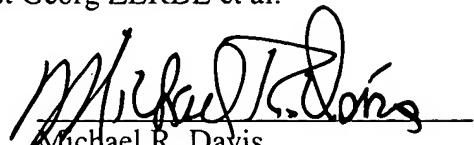
For these reasons, Applicants again take the position that the presently claimed invention is clearly patentable over the applied references.

Accordingly, the application is considered to be in condition for allowance, and such allowance is solicited.

Respectfully submitted,

Horst Georg ZERBE et al.

By:



Michael R. Davis

Registration No. 25,134
Attorney for Applicants

MRD/pth
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
September 3, 2009